TDMHMR EXECUTIVE FORMULARY COMMITTEE MINUTES
April 16, 2004

The Executive Formulary Committee convened on Friday, April 16, 2004 in Room 107D - CO Building 1. The meeting was called to order by Dr. Morgan, Chair at 9:33 a.m.

Janet Adams, MSN, RN, CNS	√	Bernardo C. Tarin-Godoy, M.D.	√
Rosha Chadwick, R.Ph.	√	Jim Van Norman, M.D.	Absent
Erlinda Devera, M.D.	√	Robert L. Ward, D.O.	√
Emilio Dominguez, M.D.	Absent	Robert Kifowit	Absent
Jeanna Heidel, Pharm.D.	√	Kenny Dudley	Absent
Robin Mallett, M.D.	Absent	Sam Shore	Absent
Jack McCoy, M.D.	Absent	Pat Martin	Absent
Victoria B. Morgan, M.D.	√	Earl Matthew, M.D.	Absent
Ann L. Richards, Pharm.D.	√	Camille Hemlock, M.D.	√
Dan Still, Pharm.D.	√	Nina Muse, M.D.	Absent
Cindy Sturdivant, B.S.N., R.N.	Absent	Steven P. Shon, M.D.	Absent

Guest Present: Sharon Tramonte, Pharm.D., San Antonio State School

Roll Call, Introductions and Announcements

Dr. Ward suggested that clinical directors be invited to the Executive Formulary Committee (EFC) meetings. This recommendation is based on the fact that JCAHO is focusing on drug formulary issues. In addition, those individuals who are on the Committee that have already undergone a JCAHO survey, indicated that having the EFC experience made their survey easier. Since the developmentally disabled regulatory process is encouraging the active participation of Pharmacy and Therapeutics Committee, it was suggested that medical directors be offered an invitation. Dr. Richards will distribute an invitation to the clinical/medical directors.

Approval of Minutes of January 30, 2004

On a motion of Ms. Chadwick, seconded by Dr. Devera, the minutes of the January 30th meeting were approved as previously distributed.

Adverse Drug Reaction Reports

The Executive Formulary Committee did not receive any adverse drug reaction reports from the field. The Committee expressed concern about the lack of reporting, especially with the JCAHO focus on adverse drug reaction reporting. It was suggested that a memo be distributed to the field encouraging the reporting of adverse drug reactions.

New Drug Applications

The Committee did not receive any new drug applications.

Quarterly Non-Formulary Drug Justification Report

The non-formulary report could not be reviewed in detail due to incomplete reports being submitted and the changeover in administrative support. The Committee discussed possible ways to improve the data analysis for the non-formulary reports. It was suggested that the percent of the non-formulary drug budget as compared to the overall drug budget be calculated. Obtaining this information is difficult with the current pharmacy system. However, it might be possible to obtain this information when the new Pharmacy software is implemented. Another suggestion was to review the number of requests per patient days as a mechanism to monitor the use of non-formulary drugs.

Polypharmacy with Atypical Antipsychotics

Dr. Hemlock discussed the use of multiple atypical antipsychotics in the same patient. Dr. Hemlock would like to explore the number of patients currently on multiple atypical antipsychotics and how many of those had been tried on clozapine (Clozaril®) prior to using multiple atypical antipsychotics. The Committee discussed the potential source for this information. BHIS is one possible source; however, the Committee did not know how accurate the data is on the State School side. Most of the State Hospitals have been audited in the past on the accuracy of their data. Most, if not all, State Hospital Pharmacies are entering their data into BHIS. It was suggested that if possible, a report be obtained from BHIS to see who is on multiple atypical antipsychotics and a report from the facilities be obtained for the same reporting time to determine the accuracy of BHIS.

Restrictive Formulary Feedback

A second memo was distributed to the field to obtain feedback from the field about the implementation of a restrictive formulary. Dr. Heidel reported that Rusk State Hospital suggested that if a restrictive formulary is implemented then cost should not be the only consideration, that psychiatric drugs not be limited and that if a drug is restricted, then an easy approval process be implemented. The Committee did not receive any negative feedback about the use of a restrictive formulary.

It was noted that the vendor drug program has already developed a Preferred Drug List (PDL) for some categories of drugs including the antipsychotics. The PDL has identified olanzapine (Zyprexa®) as a restricted drug. The agency is considering expanding the restriction of olanzapine to all patients within the agency.

The Committee suggested that the PDL established by the vendor drug program be reviewed for consideration for use as a basis for developing a restrictive formulary.

Medical Drug Preferred Agent List Work Group Update

The Work Group addressing medical drugs has not met since the last Committee meeting. It was suggested that this item be combined with the Restrictive Formulary.

Consolidation of Prescribing Psychotropic Rules - MHMR

The proposed consolidated rules have been submitted to Policy Development.

Nefazodone (Serzone®) Purchases by Facility and Feedback

At the previous meeting, it was recommended that nefazodone be deleted from the Formulary. Dr. Tramonte completed the purchase history for nefazodone. For a one-year period, 10,200 tablets were purchased for $10,232.63 by eleven facilities, mainly State Hospitals. A review of the previous three months showed that 1,640 tablets were purchased for $997.25 by 7 facilities. The Committee did not receive any feedback from the field regarding the deletion of nefazodone from the Formulary. On a motion of Dr. Ward, seconded by Dr. Devera, the recommendation to delete nefazodone from the Formulary was approved.

Atypical Antipsychotic Package Insert Change

Quetiapine (Seroquel®), clozapine (Clozaril®) and recently aripiprazole (Abilify®) have changed their package inserts to reflect the warning about hyperglycemia and diabetes mellitus with the atypical antipsychotics. Previously, olanzapine (Zyprexa®) and risperidone (Risperdal®) changed their package insert. The only remaining atypical antipsychotic that has not changed its package insert is ziprasidone (Geodon®).

Eli Lilly issued a warning about a higher incidence of stroke among elderly patients with dementia who were being treated with olanzapine. This is similar to the information that was previously distributed about risperidone (Risperdal®). It was recommended that a memo be distributed to the field regarding the olanzapine warning.

Atypical Antipsychotic Audit Parameters

Since the FDA has issued a class warning about the development of hyperglycemia with the atypical antipsychotics and five atypical antipsychotics have already changed their package insert, it was recommended that the atypical antipsychotic audit criteria be the same regarding glucose monitoring.

In reviewing the Internal Medicine News, March 1, 2004, it was suggested that a fasting plasma glucose be obtained at baseline, 12 weeks and then annually. Currently, a fasting blood glucose is obtained quarterly with clozapine (Clozaril®) and olanzapine (Zyprexa®) only. The Committee discussed the feasibility of outpatient clinics monitoring fasting blood glucose. For many patients, it is very difficult for them to keep an appointment with the psychiatrist. Requiring these patients to obtain a fasting blood glucose would almost be impossible. Hospitalized patients can easily obtain a fasting plasma glucose level.

The Committee recommended that blood glucose levels be monitored at baseline, at three months after initiation, at least annually and as clinically indicated for the atypical antipsychotics. On a motion of Dr. Tarin-Godoy, seconded by Dr. Still, the recommendation to monitor blood glucose with the atypical antipsychotic was approved.

The Committee reviewed the monitoring of lipids. The Medicine News, March 1, 2004 recommends monitoring fasting lipid profile at baseline, 12 weeks and every five years. The Committee recommended that a fasting lipid

profile be obtained at baseline, at three months after initiation, every 5 years and as clinically indicated with the atypical antipsychotics. On a motion of Dr. Tarin-Godoy, seconded by Dr. Ward the recommendation to monitor lipids was approved.

The Committee also recommended that the BMI and blood pressure be obtained on a quarterly basis. The BMI and blood pressure recommendation is not being included as a requirement in the audit parameters as it is only a recommendation.

The Committee recognizes that the development of metabolic syndromes may be more prone to occur with certain atypical antipsychotics. However, in accordance with current FDA recommendations, the Committee is requiring these guidelines be followed for all atypical antipsychotics in this entire class.

Risperidone long acting injection (Risperdal Consta®) Medication Error and Adverse Drug Reaction Review

Since risperidone long acting injection was approved when it was just released on the market, the product is being reviewed for medication errors and adverse drug reactions. Dr. Tramonte completed a review of the literature including Medline, PubMed, CEDER and a broad internet search. The search proved negative for medication errors and adverse drug reactions for the long acting risperidone injection.

Minor Changes to the Formulary

In preparation for implementing the new pharmacy software system and the implementation of computerized prescriber order entry, several drug products have been identified as not being on formulary, needing to be deleted from formulary and needing to be corrected.

The following is a listing of drug products that need to be added to the Formulary:

- Amphetamine mixture (Adderall®) tablet:20 mg
- Amphetamine mixture Adderall®) XR capsule: 20 mg
- Aripiprazole (Abilify®) tablet: 5 mg
- Azithromycin (Zithromax®) tablet: 600 mg
- Buspirone (BuSpar®) tablet: 15 mg
- Citalopram (Celexa®) tablet: 10 mg
- Delavirdine (Rescriptor®) tablet: 200 mg
- Desmopressin (DDAVP®) tablet: 0.1 mg, 0.2 mg
- Dexamethasone (Decadron®) tablet: 0.5 mg
- Didanosine (Videx®) DR capsule: 250 mg
- Divalproex (Depakote®) ER tablet: 250 mg
- Fluconazole (Diflucan®) tablet: 200 mg
- Gentamicin topical cream: 0.1%
- Gentamicin topical ointment: 0.1%
- Glucose oral gel
- Glucose tablets
- Lidocaine injection: 1%, 2%
- Methylphenidate (Concerta®) ER tablet: 54 mg
- Metoprolol (Toprol®) XL tablet: 25 mg
- Mirtazapine (Remeron®) tablet: 45 mg
- Morphine CR tablet: 60 mg
- Morphine tablet, sublingual: 10 mg
- Olanzapine (Zyprexa®) Zydis™ tablet: 15 mg, 20 mg

- Olanzapine (Zyprexa®) tablet: 15 mg, 20 mg
- Polycarbophil (FiberCon®, Fiber-Lax®) tablet: 625 mg
- Sertraline (Zoloft®) oral concentrate: 20 mg/ml
- Tiagabine (Gabitril®) tablet: 2 mg
- Tizanidine (Zanaflex®) tablet: 2 mg – **Reserve Use**
- Water for injection: 5 ml

The following products are recommended for deletion from the Formulary:

- Loxapine (Loxitane®) injection
- Perphenazine (Trilafon®) injection

The following changes were recommended for the Formulary:

- Change levodopa/carbidopa to carbidopa/levodopa
- Change the guaifenesin/dextromethorphan (Robitussin DM®) entry from 100 mg to 10 mg

On a motion of Dr. Heidel, seconded by Dr. Ward, the recommended changes were approved. It was recommended that minor changes to the Formulary be reviewed and approved by Dr. Morgan and Dr. Richards.

Proposed Drug Deletion List - Dermatological Agents, Part II

The Committee did not receive any comments from the field about the proposed deletions for the dermatological agents. On a motion of Dr. Ward, seconded by Dr. Heidel, the motion to delete the dermatological agents was approved.

TDMHMR Drug Formulary Sectional Review- Psychotropic Agents

Dr. Still provided the review of the dermatological agents with his recommendations. Attachment A. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment A).

Dr. Still recommended the addition of the following dosage strengths for products currently on Formulary:

- Mesylate form of paroxetine (Pexeva™): 10 mg, 20 mg, 30 mg, 40 mg
- Amphetamine mixture (Adderall®) tablets: 12.5 mg, 15 mg, 20 mg, 25 mg, 30 mg
- Bupropion – add the trade name Zyban®
- Bupropion tablet, sustained release: 200 mg
- Buspirone tablet: 15 mg, 30 mg
- Citalopram tablet: 10 mg
- Diazepam gel, rectal: 5 mg/ml (5 mg, 10 mg, 15 mg, 20 mg)
- Divalproex tablet, extended release: 250 mg
- Escitalopram tablet: 5 mg
- Fluoxetine tablet: 20 mg
- Fluvoxamine tablet: 25 mg
- Hydroxyzine – add the trade name Vistaril®
- Hydroxyzine suspension: 25 mg/5 ml
- Methylphenidate tablet, extended release; 27 mg, 54 mg
- Mirtazapine, rapid dissolving: 15 mg, 30 mg, 45 mg
- Olanzapine tablet: 15 mg, 20 mg
- Olanzapine Zydis: 20 mg

- Olanzapine intramuscular: 10 mg/2 ml
- Risperidone – add the trade name Risperdal M-Tab®

Dr. Still recommended the deletion of the following dosage strengths/formulations.

Generic Name	Brand Name	Dosage forms to be deleted	Dosage forms still available
Chlordiazepoxide	Librium®	Tablet: 5 mg, 10 mg, 25 mg	Capsule: 5 mg, 10 mg, 25 mg
Desipramine	Norpramin®	Capsule: 25 mg, 50 mg	Tablet: 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg
Fluphenazine	Permitil®	Concentrate: 5 mg/ml with 1% alcohol	Concentrate: 5 mg/ml with 14% alcohol Elixir: 2.5 mg/5 ml with 14% alcohol Injection, as decanoate: 25 mg/ml Injection, as hydrochloride: 2.5 mg/ml Tablet: 1 mg, 2.5 mg, 5 mg, 10 mg
Perphenazine	Trilafon®	Concentrate, oral: 16 mg/5 ml Injection: 5 mg/ml	Tablet: 2 mg, 4 mg, 8 mg, 16 mg
Thioridazine	Mellaril®	Suspension, oral: 25 mg/5 ml, 100 mg/ml	Tablet: 10 mg, 15 mg, 25 mg, 50 mg, 100 mg, 150 mg, 200 mg
Thiothixene	Navane®	Concentrate, oral: 5 mg/ml	Capsule: 1 mg, 2 mg, 5 mg, 10 mg, 20 mg
Trifluoperazine	Stelazine®	Concentrate, oral: 10 mg/ml Injection: 2 mg/ml	Tablet: 1 mg, 2 mg, 5 mg, 10 mg

On a motion of Dr. Ward, seconded by Dr. Tarin-Godoy, the motion to delete these products was approved. Feedback will be obtained from the field.

Sectional Review for July 2004

The cardiovascular agents will be reviewed at the next meeting. However, due to the implementation of the new pharmacy software system this summer, it is possible that this review will not be completed in time for the July meeting.

Next Meeting Date

The next meeting was scheduled for July 23, 2004.

Adjourn

There being no further business, the meeting was adjourned at 12:31 p.m.

Approved:

Victoria B. Morgan, M.D., Chairman

Attachments

Attachment A –Psychotropic Agents Class Review & Cost Review and Alphabetical Listing

Minutes Prepared by:
Ann L. Richards, Pharm.D.
Rosha Chadwick